

PRIA Renegotiation Form

Decision	Registration Number	Petition
548608	91960-1	

Chemical Name	BIFENTHRIN TECHNICAL
Company Name	GENSOURCE INC.
Fee Category	R351X2
PRIA Decision Time Frame	8M
Original PRIA Due Date	2019-11-04
Proposed New PRIA Due Date	2019-12-04
Current and Previous Negotiated Dates	

Negotiated Due Date Reason

Additional Data Required:	
<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other	
Comments:	

Data Deficiencies:	
<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
Comments:	

Late Risk Assessment:	
<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	

Interim Considerations:	
<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	

☐ 86-5 Deficiencies need to be addressed
 ☐ Endangered Species Concerns
 ☐ Data Not Submitted
 ☐ Failure to Respond to Deficiencies
 ☒ Other - Comment Field
 ☐ Risk Issues Environmental
 ☐ Risk Issues Human Health
 ☒ CSF
 ☒ Label
 ☐ Public Process
 ☐ Impurities Review
 ☐ Administrative-FR Notice
 ☐ Other - No Reason Selected in Webform

Summary of Deficiency Type(s)

☐ Agency Initiated
 ☐ Registrant Initiated

Is "Fix" in-house?

Describe Interactions with Company(Describe when Contacted and Company's Response including response to Previous Negotiated Due Dates:)

Contacted registrant on 10/29 requesting an extension. Registrant agreed to the extension on the same day. This is the first renegotiation for this CSF amendment to add an unregistered source of active ingredient.

"75 Date" Letter Sent?

No

Reason for None

NA

Registrant Notified that this is the Last Negotiation?

NA

Rationale for Proposed Due Date: Additional time is requested to complete the product chemistry review and any associated label revisions.

Issue(s) Describe in Detail: The Product Chemistry review is not yet complete. The review is anticipated to come in on 10/31. We renegotiated for a one month extension to allow the review to be finalized and complete any associated label work. When did the action actually get to CITAB? 3/27/19 Is this included in CITAB spreadsheet? Yes, estimated completion date is 10/31/19 Do we expect to complete the PC review before the renegotiated date? Yes

Comment(s):

Approved /Disapproved:

Approved

Date of Final Decision

Fri Nov 01 07:13:42 EDT 2019 Richard Keigwin (RKEIGWIN) from IO (Host IP Address: 161.80.156.219)

e-Signature:

Richard Keigwin (RKEIGWIN) from IO (Host IP Address: 161.80.156.219)